IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen") by way of Complaint against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Defendants"), alleges as follows:

PARTIES

1. Amgen is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

2. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

3. Upon information and belief, Teva USA is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israel corporation having a principal place of business at 5 Basel Street, Petah Tikva, Israel.

5. Upon information and belief, Teva Ltd. is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for infringement of U.S. Patent No. 9,375,405 (the "'405 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(e)(2), 271(a), 271(b), and 271(c), and for a declaratory judgment of infringement of the '405 patent under 28 U.S.C. §§ 2201 and 2202. This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") No. 090539 seeking approval to manufacture, use and/or sell cinacalcet hydrochloride tablets (EQ 90 mg base) ("Defendants' ANDA products").

JURISDICTION AND VENUE

7. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. This court has personal jurisdiction over Teva USA because, *inter alia*, it is a Delaware corporation. Upon information and belief, Teva USA, directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and derives substantial revenue from the use or consumption of Teva USA's products in the State of Delaware. Upon information and belief, Teva USA is registered with the Delaware Board of Pharmacy as "Pharmacy-Wholesale" (License Nos. A4-0001468 and A4-0001447) and a "Distributor/Manufacturer CSR" (License Nos. DM-0007115 and DM-0006546). Upon information and belief, Teva USA is registered to do business in Delaware. Upon information and belief, Teva USA maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporate Creations Network Inc., located at 3411 Silverside Road, Tatnall Building Ste. 104, Wilmington, DE 19810. In addition, Teva USA has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See, e.g.*, *The Brigham and Women's Hospital, Inc. et al. v. Teva Pharms USA Inc. et al*., C.A. No. 08-464-HB; *Endo Pharmaceuticals Inc. et al. v. Teva Pharms USA, Inc. et al.*, C.A. No. 14-1389-RGA; *Acorda Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 14-941-LPS. Further, Teva USA has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See e.g., Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 17-093 (D. Del.).

9. This court has personal jurisdiction over Teva Ltd. because, *inter alia*, upon information and belief, Teva Ltd. directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware. Upon information and

belief, Teva USA acted in concert with and/or with the assistance of Teva Ltd. to file ANDA No. 090539. Upon information and belief, Teva USA and Teva Ltd., acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA products in the United States, including in Delaware, upon approval of ANDA No. 090539, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of Delaware. In addition, Teva Ltd. has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See, e.g.*, *The Brigham and Women's Hospital, Inc. et al. v. Teva Pharms USA Inc. et al.*, C.A. No. 08-464-HB. Further, Teva Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See e.g., Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 17-093 (D. Del.).

10. In the alternative, this Court has jurisdiction over Teva Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Teva Ltd. because, *inter alia*, this action arises from actions of Teva Ltd. directed toward Delaware, and because Teva Ltd. has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Teva Ltd. regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, Teva Ltd. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

11. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE PATENT-IN-SUIT

12. On June 28, 2016, the ’405 patent, titled “Rapid Dissolution Formulation of a Calcium Receptor-Active Compound,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”).

13. The ’405 patent is assigned to Amgen and Amgen is the owner of the ’405 patent.

14. Amgen is the holder of an approved New Drug Application (“NDA”) No. 21-688 for cinacalcet hydrochloride tablets which the U.S. Food and Drug Administration (“FDA”) approved on March 8, 2004. Cinacalcet hydrochloride is a calcium receptor-active compound.

15. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

16. The ’405 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for NDA No. 21-688.

17. The claims of the ’405 patent are directed to pharmaceutical compositions comprising cinacalcet hydrochloride.

BACKGROUND ON SENSIPAR®

18. Cinacalcet hydrochloride is the active ingredient in SENSIPAR®, a medication marketed and sold in tablet form by Amgen. Amgen received FDA approval to market SENSIPAR® (cinacalcet hydrochloride) on March 8, 2004 to treat secondary

hyperparathyroidism ("HPT") in patients with chronic kidney disease ("CKD") on dialysis and hypercalcemia in patients with parathyroid carcinoma.

19. Secondary HPT is a condition that is caused when the parathyroid glands located in the neck produce too much parathyroid hormone in response to low blood calcium and is associated with CKD patients. SENSIPAR® helps to lower the amount of parathyroid hormone, calcium, and phosphorus concentrations in the blood.

20. SENSIPAR® is also indicated for use in lowering calcium levels in the blood for patients with parathyroid cancer. Patients with parathyroid cancer can develop severe hypercalcemia (an excessive amount of calcium in the blood). Removal of the parathyroid was the only available therapy for parathyroid cancer before SENSIPAR®.

21. SENSIPAR® is a first-in-class molecule developed by scientists to treat an unmet need in patients suffering from secondary HPT and parathyroid carcinoma.

22. On February 25, 2011, Amgen also received FDA approval to market SENSIPAR® to treat severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

23. For SENSIPAR®, the Orange Book lists U.S. Patent Nos. 6,011,068 ("the '068 patent"), 6,031,003 ("the '003 patent"), 6,313,146 ("the '146 patent"), and previously listed U.S. Patent No. 6,211,244 ("the '244 patent") (collectively, "Earlier Listed Patents").

24. The Orange Book also lists, more recently, the '405 patent and its parent, U.S. Patent No. 7,829,595 ("the '595 patent").

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENT-IN-SUIT

25. Upon information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

26. Defendants reviewed certain commercial and economic information regarding Amgen's SENSIPAR® and decided to file an ANDA seeking approval to market a generic version of SENSIPAR®.

27. On June 12, 2008, Amgen received a letter dated June 11, 2008 from Teva USA notifying Amgen that Teva USA had filed ANDA No. 090539 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to commercially manufacture, use, sell, and/or import Defendants' ANDA products. ANDA No. 090539 seeks FDA approval to market Defendants' ANDA products prior to the expiration of the Earlier Listed Patents. The stated purpose of Teva USA's June 11, 2008 letter was to notify Amgen that ANDA No. 090539 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") alleging that the claims of the Earlier Listed Patents were invalid or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or import of Defendants' ANDA products.

28. In a separate action, *The Brigham and Women's Hospital, Inc. et al. v. Teva Pharms USA Inc. et al.*, 08-cv-00464 (D. Del.), Amgen asserted the Earlier Listed Patents against Defendants. Defendants were found to have infringed the asserted claims and the asserted claims were held not invalid and not unenforceable. The latest expiration date of the Earlier Listed Patents is March 8, 2018, on which Amgen's '068 patent expires.

29. On April 23, 2010, Defendants received tentative approval from the FDA for ANDA No. 090539.

30. On January 2, 2014, Amgen received a letter dated December 20, 2013 from Teva USA notifying Amgen that Teva USA had filed a second Paragraph IV Certification with regard to its ANDA No. 090539 alleging that the claims of the '595 patent, parent to the

’405 patent, were invalid or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or import of Defendants’ ANDA products.

31. The ’405 patent had not issued at the time Defendants submitted the above-mentioned Paragraph IV Certifications under § 505(j)(2)(A)(vii)(IV) of the FDCA.

32. Defendants have not sent Amgen a notice of Paragraph IV Certification alleging that the claims of the ’405 patent are invalid or will not be infringed by the commercial manufacture, use, sale, offer for sale, and/or import of Defendants’ ANDA products.

33. However, upon information and belief, Defendants are aware of the ’405 patent, and have been aware of the ’405 patent for at least several months.

34. The ’405 patent was submitted for Orange Book listing on July 22, 2016, within thirty days of issuance. Upon information and belief, Defendants would have become aware of the ’405 patent upon its listing in the Orange Book on or around July 22, 2016.

35. On September 22, 2016, Amgen filed a complaint in *Amgen Inc. v. Watson Laboratories Inc., et al.*, 16-cv-00855 (D. Del.), in which Amgen asserted the ’405 patent against Watson Laboratories, Inc. (“Watson”), Actavis Pharma Inc., and Actavis, Inc., with respect to ANDA No. 204377, filed by Watson. This action was consolidated with other related actions in *Amgen Inc. v. Aurobindo Pharma Ltd. et al.*, 16-cv-853 (D. Del.) (consolidated). Upon information and belief, Defendants are both parent companies of Watson.

36. On or about March 30, 2017, counsel for Watson contacted counsel for Amgen to initiate a conversation regarding options for resolution between the parties in the consolidated action, and named the Associate General Counsel of U.S. Intellectual Property Litigation for Teva (“Teva IP Counsel”) as the appropriate contact for Watson. Therefore, upon

information and belief, Defendants had notice of the existence of the ’405 patent at least as of March 30, 2017.

37. Upon information and belief, Defendants intend to launch their ANDA products on or shortly after March 8, 2018. In a separate action regarding pediatric exclusivity of Amgen’s SENSIPAR® product, *Amgen Inc. v. Price et al.*, 17-cv-01006-RDM (D.D.C), Teva USA filed a motion to intervene as defendant on August 14, 2017. In the motion (D.I. 26), Teva USA noted that the “FDA has already granted tentative approval for Teva and Barr to market generic versions of Sensipar®, but final approval is contingent on the expiration of Amgen’s patents.” Upon information and belief, based on the intervention, Defendants still intend to seek final approval and are preparing to launch Defendants’ ANDA products as early as March 8, 2018, the expiration date for the ’068 patent. The intervention in *Amgen Inc. v. Price et al.* indicates Defendants’ interest in launching Defendants’ ANDA products as soon as possible, as a victory for Amgen in that case will likely result in pediatric exclusivity for SENSIPAR®, and would delay the earliest possible launch date by six months.

38. Upon information and belief, based upon, *inter alia*, Defendants’ Paragraph IV Certifications to the Earlier Listed Patents and the ’595 patent, and also their motion to intervene in the *Amgen Inc. v. Price et al.* case, Defendants are seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA products prior to the expiration of the ’405 patent.

39. Pursuant to 21 U.S.C. § 355(j) and 21 C.F.R. § 314.94, Defendants are required to make a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) to each of the Orange Book listed patents, including the ’405 patent. Upon information and belief, Defendants

are aware of the ’405 patent and will file such a certification with the FDA on or before March 8, 2018.

FIRST CLAIM FOR RELIEF

40. Amgen incorporates and realleges paragraphs 1-39 above, as if set forth specifically here.

41. Defendants submitted ANDA No. 090539 to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants’ ANDA products throughout the United States, including Delaware, prior to patent expiry. By submitting the application, Defendants committed an act of infringement with respect to the ’405 patent, under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, Defendants’ ANDA products would infringe, either literally or under the doctrine of equivalents, at least claim 1 of the ’405 patent.

43. Upon information and belief, Amgen is entitled to full relief from Defendants’ acts of infringement of the ’405 patent under 35 U.S.C. § 271(e)(4).

SECOND CLAIM FOR RELIEF

44. Amgen incorporates and realleges paragraphs 1-43 above, as if set forth specifically here.

45. Upon information and belief, Defendants have made substantial preparations to sell Defendants’ ANDA products.

46. Upon information and belief, Defendants intend to commence sale of Defendants’ ANDA products immediately upon receiving approval from the FDA.

47. Defendants’ actions, including but not limited to filing, maintaining, and not withdrawing ANDA No. 090539 containing Paragraph IV Certifications to the Earlier Listed

Patents and the ’595 patent indicate a refusal to change their course of action in the face of acts by Amgen, including but not limited to Amgen’s timely listing of the ’405 patent in the Orange Book.

48. Upon information and belief, the manufacture, use, sale, offer for sale, and importation of Defendants’ ANDA products, once approved by the FDA, will infringe, either literally or under the doctrine of equivalents, induce and/or contribute to the infringement of at least claim 1 of the ‘405 patent under 35 U.S.C. § 271(a), (b) and/or (c).

49. Amgen will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Amgen has no adequate remedy at law.

50. An actual controversy exists relating to Defendants’ threatened infringement of the ’405 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Amgen respectfully requests the following relief:

A. A judgment that the claims of the ’405 patent are not invalid, are not unenforceable, and are infringed by Defendants’ submission of ANDA No. 090539 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA products prior to the expiration of the ’405 patent will constitute an act of infringement of the ’405 patent.

B. An order under 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of ANDA No. 090539 shall be a date that is not earlier than the expiration date of the ’405 patent, inclusive of any extensions.

C. An injunction under 35 U.S.C. § 271 (e)(4)(B) permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants, employees, and those acting or attempting to act in concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA products, within (or into) the United States, until after the expiration of the '405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

D. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Amgen costs, expenses, and disbursements in this action, including reasonable attorney fees.

E. A declaration under 28 U.S.C. § 2201 that if Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants, employees, and those acting or attempting to act in concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA products prior to patent expiry, it will constitute an act of infringement of the '405 patent;

F. Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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